

REMARKS

The present invention relates to a dry coagulation assay reagent having magnetic particles distributed substantially homogeneously therethrough, wherein the reagent is selected from a list of reagent combinations, and wherein the reagent contains one or more lanthanide metal compounds. Applicants have found that addition of the lanthanide metal compounds provides higher sensitivity and greater dynamic detection range in the results of the assay, and provides for an improved Protein C assay.

The Examiner has rejected the claims as originally presented under 35 U.S.C. 103 over Rosen. As noted by the Examiner, Rosen discloses in vitro methods for screening for blood coagulation disorders using metal ions. However, there is no mention of the presence of lanthanide metals in the reagent or that lanthanide metals would provide any advantage. This has also been acknowledged by the Examiner in the official action.

While the reference of Rosen discloses manganese or magnesium (both divalent metals) as useful in Protein C assays for resolution improvements, there is no suggestion that a trivalent lanthanide metal would provide any such effect. The present invention, as now claimed, requires the presence of a lanthanide metal in a coagulation assay reagent. As seen in the Figures of the present application, the lanthanide metals provide a significant differentiation in the assay results from 0% to 50% to 100%. This differentiation is significantly better even than that provided by manganese or magnesium. As such, the use of lanthanides is not obvious based upon Rosen and even if obvious, would not have been expected to provide even better differentiation and greater dynamic detection range than the

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manganese and magnesium disclosed by the reference. As such, the rejection should be withdrawn.

The objection to the title of the invention is believed to be obviated by the amendment to the claims, which now does limit the invention to reagents containing lanthanides and assays using those lanthanide containing reagents.

Applicants provide herewith a copy of the PCT Written Opinion in the corresponding PCT application, in the form of an Information Disclosure Statement. The Examiner has indicated in that written opinion that the claims do not meet the PCT requirements for patentability in light of the combination of Oberhardt '676 in view of Adema. Oberhardt '676 discloses similar types of assays and dry coagulation reagents, with the primary difference being that the '676 patent does not disclose or suggest the lanthanides. The Examiner states that Adema does disclose lanthanides as a possible additive to the reagents in determination of coagulation parameters as inhibitors of coagulation. However, there is no suggestion in these references that the addition of lanthanides in the reagents of the present invention would provide the improved sensitivity and greater dynamic detection range that has been shown with the present invention. As such, even if the Examiner were to assert obviousness of the present claims in light of these references, the data already in the present application provide unexpected and surprising improvements that are nowhere suggested by the references.

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Applicants further reserve the right to request rejoinder of certain withdrawn claims upon indication of allowability of the reagents claims (and appropriate amendment of the withdrawn claims to incorporate any limitations of the reagent claims). Upon indication of allowability, the Examiner is requested to contact Applicants' representative to discuss rejoinder.

This application is now believed to be in immediate condition for allowance.

Accordingly, the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,

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